

by herpes simplex viruses and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe form of encephalitis (inflammation of the brain). Neonatal herpes virus infections range from an mild infection to a severe generalized disease with a fatal outcome.

(b) *Classification*. Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required*. No effective date has been established of the requirement for premarket approval. See § 866.3.

[47 FR 50823, Nov. 9, 1982, as amended at 52 FR 17734, May 11, 1987]

§ 866.3320 *Histoplasma capsulatum* serological reagents.

(a) *Identification*. *Histoplasma capsulatum* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Histoplasma capsulatum* in serum. Additionally, some of these reagents consist of *Histoplasma capsulatum* antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Histoplasma capsulatum* from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of histoplasmosis caused by this fungus belonging to the genus *Histoplasma* and provides epidemiological information on the diseases caused by this fungus. Histoplasmosis usually is a mild and often asymptomatic respiratory infection, but in a small number of infected individuals the lesions may spread to practically all tissues and organs.

(b) *Classification*. Class II (performance standards).

§ 866.3330 *Influenza virus* serological reagents.

(a) *Identification*. Influenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to influenza in serum. The identification aids in the diagnosis of influenza (flu) and provides epidemiological information on influenza. Influenza is an acute respiratory tract disease, which is often epidemic.

(b) *Classification*. Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25047, June 12, 1989]

§ 866.3340 *Klebsiella* spp. serological reagents.

(a) *Identification*. *Klebsiella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), that are used in serological tests to identify *Klebsiella* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Klebsiella* and provides epidemiological information on these diseases. These organisms can cause serious urinary tract and pulmonary infections, particularly in hospitalized patients.

(b) *Classification*. Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25047, June 12, 1989]

§ 866.3350 *Leptospira* spp. serological reagents.

(a) *Identification*. *Leptospira* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Leptospira* spp. in serum or identify *Leptospira* spp. from cultured isolates derived from clinical specimens. Additionally, some of these antisera are conjugated with a fluorescent dye (immunofluorescent reagents) and used to identify *Leptospira* spp. directly from clinical specimens. The identification aids in the diagnosis of leptospirosis caused by bacteria belonging to the genus *Leptospira* and provides epidemiological information on this disease. *Leptospira* infections range from mild fever-producing illnesses to severe liver and kidney involvement producing hemorrhage and dysfunction of these organs.

(b) *Classification*. Class II (performance standards).